



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/478,222	01/05/2000	DAVID S. GARVEY	102258.346	1404

25270 7590 03/30/2004

EDWARD D GRIEFF  
HALE & DORR LLP  
1455 PENNSYLVANIA AVE, NW  
WASHINGTON, DC 20004

EXAMINER
----------

CELSA, BENNETT M

ART UNIT	PAPER NUMBER
----------	--------------

1639

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/478,222

Applicant(s)

GARVEY ET AL.

Examiner

Bennett Celsa

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 61 and 63-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61 and 63-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/03/1/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

Applicant's amendment dated 1/12/04 is acknowledged.

***Status of the Claims***

Claims 61 and 63-65 are currently pending and under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objection(s) and/or Rejection(s)***

The filing of a terminal disclaimer has overcome the provisional double patenting rejection of claims 61-65 and 70-72 over claims 100-114 of copending Application No. 09/850,081.

***Outstanding Issues, Objection (s) and/or Rejection (s)***

***Priority***

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

3. Applicant's claim for 35 U.S.C. 120 priority for

Art Unit: 1639

a. 09/145,143 (9/1/98) (US Pat. No. 6,294,517) is granted.

However, Applicant's claim for 35 U.S.C. 120 priority for:

- I. PCT US 97/ 01294 (1/97) (Published as WO 97/27749);
- II. 08/714,313 (9/96) (US Pat. No. 5,994,294); and
- III. 08/595,732 (2/96) (US Pat. No. 5,932,538)

is acknowledged BUT DENIED; since the above (I. II. And III) applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 61 and 63-65 of this application drawn to a method for treating **female impotence** with an S-nitrosothiol compound since the above applications demonstrate possession of using S-nitrosothiols to treat human male impotence but not human female impotence.

Accordingly, claim 61 and 63-65 are afforded the filing date of 9/1/98 for purposes of prior art.

### ***Discussion***

Applicant's arguments directed to the above denial of 35 USC 120 priority under 35 USC 112, first paragraph to the PCT US 97/ 01294 (1/97) (Published as WO 97/27749), . 08/714,313 (9/96) (US Pat. No. 5,994,294); and 08/595,732 (2/96) (US Pat. No. 5,932,538) applications were considered but deemed nonpersuasive for the following reasons. Initially, it is noted that the above denial was modified (e.g. changing claim numbers) in conformance with applicant's amendment.

Applicant argues that the Examiner's withdrawal (in January 22, 2002 at page 3, lines 1-2) of a new matter rejection (raised in the June 29, 2001 office action) "in view of Applicant's arguments, declaration and general incorporation by reference filed on

Art Unit: 1639

September 26, 2001" amounted to the Examiner agreeing with applicant's arguments directed to application 08/714,313 regarding new matter.

This argument is not persuasive for the following reasons.

The new matter rejection raised in the June 29, 2001 office action was as follows:

Claims 61-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (e.g. NEW MATTER REJECTION).

In the Preliminary Amendment (filed 1/5/200) claims 61-65 addressing methods for treating female impotence by administering S-nitrosothiols were newly added. Although having support for treating "female sexual dysfunctions" (e.g using S-nitrosothiols) the original specification and original claims do not support treating "female impotence" as presented in new claims 61-65 of the Preliminary Amendment. It is noted that an amendment filing along with the filing of an application (as in the present Preliminary Amendment) *does not enjoy* the status as part of the original disclosure in an application filed under 37 CFR 1.53(b) unless it is specifically referred to in the oath or declaration filed therewith (e.g. see MPEP 608.04b). IN the present instance, the oath or declaration fails to specifically refer to the Preliminary Amendment.

As described in the new matter rejection above, during the prosecution of the present application (e.g. 09/478,222) a Preliminary Amendment presenting new claims having new terminology had been advanced which was not referred to in the Declaration. The issue was thus whether the preliminary amendment claims engendered CIP status on the present application (e.g. requiring a new declaration) or whether the present application was a continuation of the parent 09/145,143 application. Thus, 35 USC 120 priority regarding applications other than the 09/145,143, to which 35 USC 120 priority has been granted, was never at issue.

In contradistinction to the previous new matter rejection, the issue raised above is denial of 35 USC 120 priority as it relates to the ability of the following earlier applications:

- I. PCT US 97/ 01294 (1/97) (Published as WO 97/27749);
- II. 08/714,313 (9/96) (US Pat. No. 5,994,294); and
- III. 08/595,732 (2/96) (US Pat. No. 5,932,538)

to satisfy 35 USC 112, first paragraph regarding claims directed to treating **human female impotence** by administering an S-nitrosothiol compound. In this regard, there is no descriptive or exemplary support in the above-cited I-III applications for treating human female impotence by administering an S-nitrosothiol compound. Applicant is also directed to their "Preliminary Amendment" filed with the CPA request dated 1/10/03 and Remarks (pages 5-9 of 14: including cited references) for why a treatment for human female impotence *is not extrapolatable or obvious* from the same impotence treatment for a human male.

Accordingly, the above denial of 35 USC 120 priority is hereby retained.

4. Claims 61 and 63-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Place et al. US Pat. No. 6,306,841 (10/01: *effective filing date Oct. 28, 1997*).

Place et al. describe and specifically claim the topical compositions (e.g. pharmaceutical) for use (e.g. see col. 2, especially lines 40-52; col. 4-6; examples/claims) of S-nitrosothiols (e.g. S-Nitroso-N-glutathione included in the present claims i.e. claim 65 item IV and claims 70 and 71) to treat female sexual dysfunction (e.g. impotence). E.g. See claims 1, 30 and 31.

5. Claims 61 and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Place et al. US Pat. No. 6,306,841 (10/01: *effective filing date Oct. 28, 1997*) and Stamler et al. WO 92/17445 US Pat. No. 5,380,758 (1/95).

Place et al. describe and specifically claim the topical compositions (e.g. pharmaceutical) for use (e.g. see col. 2, especially lines 40-52; col. 4-6; examples/claims) of S-nitrosothiols (e.g. S-Nitroso-N-glutathione included in the present claims i.e. claim 65 item IV and claims 70 and 71)) to treat female sexual dysfunction (e.g. impotence). E.g. See claims 1, 30 and 31.

The Place et al. reference teaching differs from the presently claimed invention by:

A. failing to specifically recite specific S-nitrosothiol compounds which are presently claimed (e.g. see present claim 63) e.g. S-nitroso-N-acetylcysteine, S-nitroso-captopril, S-nitroso-homocysteine; and

B. failing to teach S-nitrosothiol generics (I)-(iii) or compounds within these generics;

However, the Place et al. Reference does teach vasoactive agents NO releasing agents, such as the S-nitrosothiol compounds (e.g. see col. 9 and patent claims) can be employed interchangeably e.g. are functionally equivalent.

Stamler et al. teach that S-nitrosothiols such as S-nitroso-N-acetylcysteine, S-nitroso-captopril, S-nitroso-homocysteine and S-nitrosoglutathione; as well as S-nitrosothiol compounds within the presently claimed generics (I)-(iii) can be used

interchangeably for the vasoactive effect (E.g. on smooth muscle). Eg. See Stamler at pages 1-6, examples and claims.

Accordingly, one of ordinary skill in the art would be motivated to utilize S-nitroso-N-acetylcysteine, S-nitroso-captopril, S-nitroso-homocysteine for the S-nitrosothiols (E.g. S-nitrosoglutathione) or a S-nitrosothiol compound within the presently claimed Generics I-III in the Place et al. method due to their functional equivalence as recognized by the Stamler and/or Place references.

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to utilize S-nitroso-N-acetylcysteine, S-nitroso-captopril, S-nitroso-homocysteine for the S-nitrosothiols (E.g. S-nitrosoglutathione) or an S-nitrosothiol compound within the Generics I-III in the the Place et al. method with a reasonable expectation of success.

### ***Discussion***

Applicant's arguments directed to the above prior art rejections were considered but deemed nonpersuasive for the following reasons. Initially, it is noted that the above rejections were modified in conformance with applicant's amendment (e.g. remove cancelled claims).

Applicant argues that the granting of 35 USC 120 priority requires removal of the above document (e.g. Place reference) since it would no longer qualify as prior art.

This argument is not persuasive since the denial of 35 USC 120 priority was retained for the reasons recited above.

Accordingly, the above prior art rejections are maintained.



***New Objection(s) and/or Rejection(s)******Double Patenting***

6. Claims 61 and 63-65 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/024,550 (PG Pub 2002/0061879A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '550 claims teach a method of treating female "sexual dysfunction" (e.g. female impotence as presently claimed) by the (administrative) use of (pharmaceutical) compositions comprising S-nitrosothiol compounds within the scope of the presently claimed invention. See e.g. '550 claims 5-18, 20-32.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 1/26/04 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1639

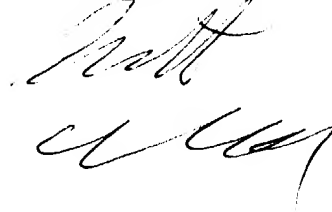
***Future Correspondences***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa  
Primary Examiner  
Art Unit 1639



BC  
March 26, 2004